

**SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF PHARMACY
AND CT INTERNATIONAL**

CT International ("Licensee") and the State Board of Pharmacy ("Board") enter into this settlement agreement for the purpose of resolving the question of whether Licensee's license will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo,¹ the parties hereto waive the right to a hearing by the Administrative Hearing commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Licensee acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges against it proven upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence on mitigation of discipline; and the right to request the recovery of attorney's fees incurred in defending this action against its license. Being aware of these rights provided to Licensee by operation of law, Licensee knowingly and voluntarily waives

¹ All statutory references are to the 2000 Revised Statutes of Missouri, as amended, unless other wise stated.

each and every one of these rights and freely enters into this settlement agreement and agrees to abide by the terms of this document, as they pertain to it.

Licensee acknowledges that it has received a copy of the investigation report and other documents relied upon by the Board in determining there was cause for discipline, along with citations to law and/or regulations the Board believes were violated. For purpose of settling, Licensee stipulates that the factual allegations contained in this settlement agreement are true and stipulates with the Board that Licensee's drug distributor license, license no. 901490, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo.

Joint Stipulation of Facts

1. The Board is an agency of the State of Missouri created pursuant to Section 338.140, RSMo, for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. Licensee holds a license from the Board as a drug distributor, license no. 901490 ("Missouri license"). Licensee's Missouri license was current and active at all times relevant herein, and is presently still active.

3. On or about January 22, 2007, Licensee's California wholesale permit, No. WLS 3575 ("California license"), was disciplined by the Board of Pharmacy, Department of Consumer Affairs, State of California ("California Board") pursuant to Cal. Bus. & Prof. Code § 4301(j) and (o), which provides in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake.

Unprofessional conduct shall include, but is not limited to, any of the following:

* * *

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

* * *

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

4. Licensee's California license was disciplined by the California Board pursuant to Cal. Bus. & Prof. Code § 4301(j) and (o) on or about January 22, 2007 because between May 15, 2003 and October 31, 2003, Licensee was in violation of Cal. Bus. & Prof. Code § 4081(a) and Cal. Admin. Code tit. 16, § 1709.1 by failing to maintain records of sale, acquisition, or disposition of dangerous drugs or dangerous devices when it received dangerous drugs from licensed wholesalers and transferred dangerous drugs to retail vendors without issuance of proper documentation.

5. Cal. Bus. & Prof. Code § 4081(a) provides:

(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with

Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

6. Cal. Admin. Code tit. 16, § 1709.1 provides:

(a) The pharmacist-in-charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy.

(b) The pharmacy owner shall vest the pharmacist-in-charge with adequate authority to assure compliance with the laws governing the operation of a pharmacy.

(c) No pharmacist shall be the pharmacist-in-charge of more than two pharmacies. If a pharmacist serves as pharmacist-in-charge at two pharmacies, those pharmacies shall not be separated by a driving distance of more than 50 miles.

(d) No pharmacist shall be the pharmacist-in-charge of a pharmacy while concurrently serving as the designated representative-in-charge for a wholesaler or a veterinary food-animal drug retailer.

(e) Notwithstanding subdivision (a), a pharmacy may designate any pharmacist who is an employee, officer or administrator of the pharmacy or the entity which owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis as the pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity which owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with documentation of the involvement of a pharmacist-in-charge designated pursuant to this subdivision with the pharmacy and efforts to obtain and designate a permanent pharmacist-in-charge.

(f) A pharmacist may refuse to act as a pharmacist-in-charge at a second pharmacy if the pharmacist determines, in the exercise of his or her professional judgment, that assuming responsibility for a second pharmacy would interfere with the effective performance of the pharmacist's responsibilities

under the Pharmacy Law. A pharmacist who refuses to become pharmacist-in-charge at a second pharmacy shall notify the pharmacy owner in writing of his or her determination, specifying the circumstances of concern that have led to that determination.

(g) A person employing a pharmacist may not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this section.

Joint Conclusions of Law

1. Section 338.055, RSMo, in pertinent part, states as follows:
 2. The board may cause a complaint to be filed with the Administrative Hearing Commission as provided by Chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his certificate or registration or authority, permit or license for any one or any combination of the following causes:

* * *

(6) Violation of, or assisting or enabling any person to violate, any provisions of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

* * *

(8) Denial of licensure to an applicant or disciplinary action against an applicant or the holder of a license or other right to practice any profession regulated by this chapter granted by another state, territory, federal agency, or country whether or not voluntarily agreed to by the licensee or applicant, including, but not limited to, surrender of the license upon grounds for which denial or discipline is authorized in this state;

* * *

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government[.]

2. 20 CSR 2220.5.030 states in pertinent part:

(2)(E) Drug distributor operations must be conducted at all times under the supervision of a properly designated manager-in-charge. The manager-in-charge must be actively involved and aware of the actual daily operations of the drug distributor operation. The manager-in-charge must be physically present at the drug distributor operation during normal business hours, except for time periods when absent due to illness, scheduled vacation or other authorized absence; and be aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the drug distributor operation. When the person who is manager-in-charge resigns or is terminated from the position, the holder of the license shall immediately notify the board office of the resignation or termination of the manager-in-charge and by notarized affidavit give the name of the new manager-in-charge.

* * *

(3) Minimum standards of practice for drug distributors shall include the following:

* * *

(J) Inventories and records shall be made available for inspection and photocopying by authorized federal, state or local law enforcement agency officials for a period of three (3) years following disposition of the drugs;

(K) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state or local law enforcement agency[.]

3. Because Licensee's California license was disciplined by the California Board pursuant to Cal. Bus. & Prof. Code § 4301(j) and (o) for violating Cal. Bus. & Prof. Code § 4081(a) and Cal. Admin. Code tit. 16, § 1709.1, Licensee's California license was

disciplined on grounds for which discipline is authorized in Missouri under § 338.055.2(6) and (15), RSMo, providing cause to discipline Licensee's Missouri license pursuant to § 338.055.2(8), RSMo.

Jointly Agreed Disciplinary Order

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Section 621.045.3, RSMo.

1. Licensee's Missouri license as a drug distributor, license no. 901490, is hereby placed on **PROBATION until FEBRUARY 21, 2010.**

2. Licensee shall pay all required fees for licensing to the Board and shall renew its license prior to October 31st of each licensing year.

3. Licensee shall comply with all provisions of Chapter 338, Chapter 195, RSMo, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" as used in this paragraph includes the State of Missouri and all other states and territories of the United States.

4. If, after disciplinary sanctions have been imposed, Licensee fails to keep its Missouri license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

5. Licensee shall report to the Board, on a preprinted form supplied by the Board office, once every six months, beginning six months after this order/agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of this disciplinary order.

6. Licensee shall make a representative available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Licensee will be notified and given sufficient time to arrange these meetings.

7. Licensee's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary order.

8. The parties to this agreement understand that the Board of Pharmacy will maintain this agreement as an open record of the Board as provided in Chapters 338, 610, and 620, RSMo.

9. The terms of this settlement agreement are contractual, legally enforceable, and binding, not merely recital. Except as otherwise contained herein, neither this settlement agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

10. Licensee hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former Board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. Section 1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this settlement agreement. The parties acknowledge that this paragraph is severable from the remaining

portions of this settlement agreement in that it survives in perpetuity even in the event that any court of law deems this settlement agreement or any portion thereof void or unenforceable.

11. Licensee understands that it may, either at the time the settlement agreement is signed by all parties, or within fifteen (15) days thereafter, submit the agreement to the Administrative Hearing Commission for determination that the facts agreed to by the parties constitute grounds for disciplining Licensee's license as a pharmacist. If Licensee desires the Administrative hearing Commission to review this agreement, Licensee may submit its request to: Administrative Hearing Commission, Truman State Office Building, Room 640, 301 W. High Street, P.O. Box 1557, Jefferson City, Missouri 65102.

12. If Licensee requests review, this settlement agreement shall become effective on the date the Administrative Hearing Commission issues its order finding that the settlement agreement sets forth cause for disciplining Licensee's license. If Licensee does not request review by the Administrative Hearing Commission, the settlement agreement goes in to effect fifteen (15) days after the document is signed by the Executive Director of the Board.

LICENSEE

By: Michael S. Kyle
CT International

Date 7/29/08

STATE BOARD OF PHARMACY

Thomas M. Gleusk
~~Debra C. Ringgenberg~~ Thomas M. Gleusk
~~Executive Director~~ Chief Inspector
State Board of Pharmacy

Date 8-11-08

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**ATTORNEYS FOR THE STATE
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